

Patented
Art 34 Amdt

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What is claimed is

1. A pharmaceutical composition for sustained release comprising as active ingredient an HMG-CoA reductase inhibitor or a pharmaceutically acceptable salt thereof, said composition comprising an inner phase (internal) and an outer phase (external), wherein at least the outer phase comprises at least one matrix former.
2. A composition according to claim 1, wherein the HMG-CoA reductase inhibitor is selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin, or, in each case, a pharmaceutically acceptable salt thereof.
3. A composition according to claim 2, wherein the HMG-CoA reductase inhibitor is pitavastatin or a pharmaceutically acceptable salt thereof.
4. A composition according to anyone of claims 1 to 3 wherein the amount of HMG-CoA reductase inhibitor or pharmaceutically acceptable salt thereof is about 5-50 weight % of the composition.
5. A composition according to anyone of claims 1 to 4 wherein the amount of HMG-CoA reductase inhibitor or pharmaceutically acceptable salt thereof is about 1-32mg.
6. A composition according to anyone of claims 1 to 5, wherein the inner phase comprises a matrix former.
7. A composition according to claim 6, wherein the matrix former of the inner phase comprises one or more types of matrix former component having different viscosities.
8. A composition according to claim 7, wherein the matrix former of the inner phase has a viscosity of about 1 to about 500 cps.
9. A composition according to any one of claims 1 to 8, wherein the matrix former of the external phase comprises one or more type of matrix former component having different viscosities.

10. A composition according to claim 9 , wherein the matrix former of the external phase has a viscosity of about 100 to about 100000cps.
11. A composition according any one of claims 1 to 10, wherein the matrix former is selected from the group consisting of polyethylene glycol, polyvinylpyrrolidone, polyvinyl alcohol, hydrophilic polymers such as hydroxypropylcellulose, hydroxymethylcellulose, and hydroxypropylmethylcellulose or the like.
12. A composition according to claim 11, wherein the matrix former is hydroxypropylmethylcellulose (HPMC).
13. A composition according to claim 12 wherein the amount of HPMC as a matrix former is about 1-60 weight % of the composition.
14. A composition according to anyone of claims 1 to 13, wherein said composition comprises a stabilizer .
15. A composition according to claim 14, wherein the stabilizer is magnesium aluminium metasilicate (neusilin).
16. A composition according to claim14 or 15, wherein the amount of the stabilizer is about 1-15 weight % of the composition.
17. A method of treatment of hyperlipidemia, hypercholesterolemia and atherosclerosis, as well as other diseases or conditions in which HMG-CoA reductase is implicated comprising administering to a patient in need thereof a therapeutically effective amount of a composition according to any one of claims 1 to 16.
18. Use of the composition according to any one of claims 1 to 16 in the manufacture of a medicament for use in the treatment or prevention of a cardiovascular disease, e.g., hypercholesterolemia, hyperproteinemia and /or atherosclerosis.